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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,299	09/18/2003	Maurizio Zanetti	A-58624-2/RFT/RMK	8409

32940 7590 08/25/2004

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EXAMINER

TRAVERS, RUSSELL S

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/667,299	ZANETTI, MAURIZIO	
	Examiner	Art Unit	
	Russell Travers, J.D.,Ph.D	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-5 is/are pending in the application.
 - 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 1-5 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: ____.

The Information disclosure statement filed March 19, 2004 has been received and entered into the file.

Claims 1-5 are presented for examination.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. § 102(b) as being anticipated by Riede et al.

Riede et al teach the effectiveness of the claimed compounds in-vitro (see page 2, lines 35-43). Applicants' attention is directed to *Ex parte Novitski*, 26 USPQ2d 1389 (BOPA 1993) illustrating anticipation resulting from inherent use, absent a *haec verba* recitation for such utility. In the instant application, as in *Ex parte Novitski*, *supra*, the claims are directed to preventing a malady or disease with old and well known compounds or compositions. It is now well settled law that administering compounds inherently possessing a protective utility anticipates claims directed to such protective use. Arguments that such protective use is not set forth *haec verba* are not probative. Prior use for the same utility clearly anticipates such utility, absent limitations distancing the proffered claims from the inherent anticipated use. Attempts to distance claims from anticipated utilities with specification limitations will not be successful. At page 1391, *Ex*

parte Novitski, *supra*, the Board said "We are mindful that, during the patent examination, pending claims must be interpreted as broadly as their terms reasonably allow. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). As often stated by the CCPA, "we will not read into claims in pending applications limitations from the specification." *In re Winkhaus*, 52 F.2d 637, 188 USPQ 219 (CCPA 1975)." In the instant application, Applicants' failure to distance the proffered claims from the anticipated prophylactic utility, renders such claims anticipated by the prior inherent use.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1 and 5 are rejected under 35 U.S.C. § 103 as being unpatentable over Riede et al, of record, and Schneider et al, of record. Riede et al and Schneider et al teach humic acid as old well known and useful as therapeutic for retroviral infections. It is noted that this therapy is taught as effective in preventing both cellular effects resulting from viral infection, and affecting viral replication.

Claims 1 and 5 differ from the primary reference in not teaching physiological events underlying the therapy herein claimed. This deficiency is cured by the well known principle in patent law that mode of action elucidation fails to impart patentable moment to otherwise obvious subject matter.

Applicant's claims are directed to anti-HIV therapy, and only secondarily recite effecting some biochemical pathway with the old and well known compounds, wherein these compounds are well known for the envisioned ultimate utility. Arguments that Applicant's claims are not directed to the old and well known ultimate claimed utility for these compounds are not probative. It is well settled patent law that mode of action elucidation fails to impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not cause a claim drawn to those things to distinguish over the prior art.". Additionally, where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter, may in fact be an inherent characteristic of the prior art, it possesses the authority to

requires the applicant to prove that the subject matter shown to be in the prior art dose not possess the characteristic relied on. In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, not those alternative benefits recited. The ultimate utility for the claimed compounds is old and well known, rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103.

Riede et al and Schneider et al teach humic acid, humic acid salts and humic acid derivatives as useful for treating the HIV etiological agent claimed herein. Although the Examiner cited prior art fails to recite the biochemical lesions averred by Applicant, effective therapy would have been viewed as ameliorating all possible biochemical lesions in the etiological agent effected. Possessing the Examiner cited prior art teachings, the skilled artisan would have been motivated to employ various humic acid compounds to treat the HIV infections, in the manner recited in claims 1 and 5, absent information to the contrary, and enjoy a reasonable expectation of success. The ultimate utility for the claimed compounds is old and well known, rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103.

Claims 2-4 are rejected under 35 U.S.C. § 103 as being unpatentable over Riede et al and Schneider et al as set forth above for claims 1 and 5 in further view of Lange et al. Riede et al and Schneider et al teach humic acid as old, well known, useful, and therapeutic for retroviral infections. It is noted that this therapy is taught as effective in

preventing both cellular effects resulting from viral infection, and affecting viral replication. Riede et al and Schneider et al teach the claimed compounds as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. This medicament, humic acid, is taught as old well known and useful as therapeutic for retroviral infections. It is noted that this therapy is taught as effective in preventing both cellular effects resulting from viral infection, and affecting viral replication. Claims 2-4, and the primary references, differ as to:

- 1) the recitation of immunostimulatory activity residing in these medicaments, and
- 2) use of these compounds as adjuvants.

Attention is directed to Lange et al teaching humic acid as providing immunostimulatory action on rats upon oral administration. Examiner notes the stimulation was effective upon administration of a single dose, motivating the skilled artisan to employ this compound as an adjuvant in those individuals experiencing "depressed immune function" (see claim 3) as claimed herein. As stated above Riede et al teach the instant claimed compounds as useful for in-vitro use (see Riede et al page 2, lines 35-43). Possessing these teachings the skilled artisan would have been motivated to employ humic acid for any immunostimulation use, to include the anti-HIV use herein envisioned, and enjoy a reasonable expectation of therapeutic success, absent information to the contrary

Examiner notes an adverse decision with regard to claims 1 and 5 by the Board of Patent Appeals and Interferences. Absent amendments, illustrations of unexpected

benefit residing in the claims as presented, or a successful appeal in the Federal Courts, the validity of the instant rejections with regard to these claims is factual, and thus, refractory to rebuttal argument.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Travers, J.D.,Ph.D whose telephone number is 571-272-0631. The examiner can normally be reached on Monday to Thursday from 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**Russell Travers, J.D, Ph.D.
Primary Examiner
Art Unit 1617**